



[Billing Code 4140-01-P]

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Prospective Grant of Start-up Exclusive Evaluation Patent License: Development of Autologous Tumor-reactive T Cells Isolated from Peripheral Blood for the Treatment of Metastatic Follicular Thyroid Cancer and Metastatic Soft Tissue Sarcomas

AGENCY: National Institutes of Health

ACTION: Notice

SUMMARY: The National Cancer Institute, National Institutes of Health, Department of Health and Human Services, is contemplating the grant of a Start-up Exclusive Evaluation Patent License to MedGene Therapeutics, Inc. (“MedGene”) located in Bethesda, MD to practice the inventions embodied in the patent applications listed Supplementary Information section of this notice.

DATES: Only written comments and/or applications for a license which are received by the NCI Technology Transfer Center on or before [INSERT DATE 15 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER] will be considered.

ADDRESSES: Requests for copies of the patent applications, inquiries, and comments relating to the contemplated Start-up Exclusive Evaluation Patent License should be directed to: Andrew Burke, Ph.D., Licensing and Patenting Manager, NCI Technology Transfer Center, 9609 Medical Center Drive, RM 1E530 MSC 9702, Bethesda, MD 20892-9702 (for business mail), Rockville, MD 20850-9702 Telephone: (240)-276-5530; Facsimile: (240)-276-5504; E-mail: andy.burke@nih.gov

SUPPLEMENTARY INFORMATION:

United States Provisional Patent Application No. 61/771,251 filed March 1, 2013, entitled “Methods of Producing Enriched Populations of Tumor Reactive T Cells from Peripheral Blood” [HHS Reference No. E-085-2013/0-US-01]; and PCT Application No. PCT/US2013/038813 filed April 30, 2013 entitled “Methods of Producing Enriched Populations of Tumor Reactive T Cells from Peripheral Blood” [HHS Reference No. E-085-2013/0-PCT-02] (and U.S. and foreign patent applications claiming priority to the aforementioned applications).

The patent rights in these inventions have been assigned to the government of the United States of America.

The prospective Start-up Exclusive Evaluation Patent License territory may be worldwide and the field of use may be limited to the development, manufacture and commercialization of autologous tumor-reactive peripheral blood T cell therapy products as set forth in the Licensed Patent Rights for the treatment of metastatic follicular thyroid cancer and metastatic soft tissue sarcomas in humans.

The present invention describes a method of selecting highly tumor-reactive T cells from autologous peripheral blood samples based on the expression of two specific T cell surface markers: Programmed cell death protein 1 (PD-1; CD279) and/or T cell Ig- and mucin-domain-containing molecule-3 (TIM-3). Following selection, isolated cells may be expanded and reinfused into the donor patient as part of an adoptive cell transfer therapeutic regimen. The disclosed method may be advantageous over existing approaches which rely on the isolation of T cells from tumor samples since it eliminates the cost and complications associated with tumor resection, as well as provides a T cell

product for patients without resectable lesions.

This notice is made in accordance with 35 U.S.C. 209 and 37 CFR Part 404. The prospective Start-up Exclusive Evaluation Patent License will be royalty bearing and the may be granted unless within fifteen (15) days from the date of this published notice, the National Cancer Institute receives written evidence and argument that establishes that the grant of the license would not be consistent with the requirements of 35 U.S.C. 209 and 37 CFR Part 404.

Complete applications for a license in the prospective field of use that are timely filed in response to this notice will be treated as objections to the grant of the contemplated Start-up Exclusive Evaluation Patent License. Comments and objections submitted to this notice will not be made available for public inspection and, to the extent permitted by law, will not be released under the *Freedom of Information Act*, 5 U.S.C. 552.

September 20, 2016

Dated

Richard U. Rodriguez, M.B.A.

Associate Director

Technology Transfer Center

National Cancer Institute

[FR Doc. 2016-23048 Filed: 9/23/2016 8:45 am; Publication Date: 9/26/2016]